

**The Michigan Department of Community Health
Institutional Review Board for Human Subjects Research**
Capitol View Building, 7th Floor, 201 Townsend Street, Lansing, MI 48913
Phone: 517/241-1928 Fax: 517/335-8297

MDCH IRB REVIEW APPLICATION

Authority: Code of Federal Regulations Title 45 Part 46

Completion of Sections 1-4 is mandatory for all applications. Note: To complete this application, type answers directly into shaded answer areas. To check a box, put your cursor on the box, double click and choose “checked.”

SECTION 1 – PROJECT IDENTIFICATION (completion of this section is mandatory)

- 1.1 Title of the Project** (title must be the same on all study documents):
- 1.2 “Responsible MDCH Employee”** (MDCH employee responsible for the Department’s role in this research):
- 1.3 “Responsible MDCH Employee’s” Signature:** (required to assure departmental responsibility for the protection of human subjects and adherence to MDCH IRB requirements):
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- 1.4 “Responsible MDCH Employees’s” Agency and Bureau, Office, or Center:**
- 1.5 Source of Funding** (include both the name and type of agency, e.g., CDC-federal):
- 1.6 Grant Number** (**REQUIRED** for all federally funded projects):
- 1.7 Project Type** (Check all that apply)
- ☐ Direct human subject participation involving invasive treatments, procedures, or experimentation.
- ☐ Direct human subject participation using surveys, interviews, focus groups, observations, etc.
- ☐ Indirect human subject participation using human data or biological specimens that were collected, or will be collected, for non research purposes, or material that will be discarded.
- 1.8 Check which FDA-regulated test articles (i.e., investigational drugs, biologics or devices) will be used in this project?** (Check all that apply)
- ☐ No test article used
- ☐ Drug or biologic used IND#: Trial Phase:
- ☐ Device used IND#: Risk level (significant or insignificant):
- 1.9 What is the projected date to begin this research?**
- 1.10 What is the projected date to complete this research?**
- 1.11 List any other IRBs that will review this project:**
- 1.12 Describe any potential conflicts of interest between the researchers and the study sponsors:**
- 1.13 Name of Principal Investigator (if not the responsible MDCH employee listed in 1.1):**

*****END OF SECTION 1*****